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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ESPERION THERAPEUTICS, INC., Plaintiff. v. MICRO LABS USA, INC. and MICRO LABS LIMITED, Defendants.	Honorable Julien X. Neals, U.S.D.J. Civil Action No. 24 CV 5921 (JXN)(CLW) **DEFENDANTS MICRO LABS LIMITED AND MICRO LABS USA, INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Micro Labs Limited and Micro Labs USA, Inc. (collectively "Micro Labs") hereby files their ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS to the First Amended Complaint of Plaintiff Esperion Therapeutics, Inc. ("Plaintiff" or "Esperion") as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Micro Labs denies all allegations in Plaintiff's First Amended Complaint except those specifically admitted below:

1. This is an action for patent infringement by Esperion Therapeutics, Inc. ("Esperion") under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Micro Labs USA, Inc. and Micro Labs Limited (collectively "Micro Labs"). This action arises out of Micro Labs' submission of Abbreviated New Drug Application ("ANDA") No. 219182 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of

NEXLETOL® prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584 (collectively, the "Asserted Patents").

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Micro Labs admits that Plaintiff purports to being a civil action for patent infringement on U.S. Patent No. 11,760,714 (the '714 patent), U.S. Patent No. 11,613,511 (the '511 patent), and U.S. Patent No 11,926,584 (the '584 patent) (collectively, the "Asserted Patents"). Micro Labs also admits to submitting to the FDA an ANDA under Section 505(j) of the Federal Food, Drug, and cosmetic Act ("the Act") seeking approval for proposed bempedoic acid tablets (the "Micro Labs ANDA Product") prior to the expiration of the '714 patent, the '511 patent and the '584 patent. All remaining allegations are denied.

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 2, and on that basis denies these allegations.

3. Upon information and belief, Defendant Micro Labs USA, Inc. ("Micro Labs USA") is a corporation organized and existing under the laws of the State of New Jersey, with its principal place of business at 220 Davidson Avenue, Suite 402, Somerset, NJ 08873.

ANSWER: Micro Labs USA, Inc. admits that it is a company organized and existing under the laws of New Jersey, having a principal place of business at 220 Davidson Avenue, Suite 402, Somerset, NJ 08873.

4. Upon information and belief, Micro Labs USA is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs).

ANSWER: Micro Labs USA, Inc. admits that it distributes and sells drug products throughout the United States. All remaining allegations are denied.

5. Upon information and belief, Micro Labs USA directly or through its affiliates, markets and sells drug products throughout the United States, including in the state of New Jersey.

ANSWER: Micro Labs USA, Inc. admits that it distributes and sells drug products throughout the United States. All remaining allegations are denied.

6. Upon information and belief, Defendant Micro Labs Limited ("MLL") is a corporation organized and existing under the laws of India, having a place of business at 31, Race Course Road, Bangalore, India 560 001.

ANSWER: Micro Labs Ltd. admits that it is a company organized and existing under the laws of India, having a place of business at 31, Race Course Road, Bangalore, India 560 001.

7. Upon information and belief, MLL is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

ANSWER: Micro Labs Ltd. admits that it sells drug products and that such drug products are distributed to the United States. All remaining allegations are denied.

8. Upon information and belief, MLL directly or through its affiliates, including Micro Labs USA, markets and sells drug products throughout the United States, including in the state of New Jersey.

ANSWER: Micro Labs Ltd. admits that it sells drug products and that such drug products are distributed to the United States. Micro Labs admits that Micro Labs USA, Inc. is a subsidiary of Micro Labs Ltd. All remaining allegations are denied.

9. Upon information and belief, Micro Labs USA is a wholly owned subsidiary of MLL.

ANSWER: Micro Labs admits that Micro Labs USA, Inc. is a subsidiary of Micro Labs Ltd. All remaining allegations are denied.

10. Upon information and belief, MLL directs or controls the operations, management, and activities of Micro Labs USA in the United States.

ANSWER: Micro Labs admits that Micro Labs USA, Inc. is a wholly-owned subsidiary of Micro Labs Ltd. The remaining allegations of paragraph 10 of the First Amended Complaint contain conclusions of law to which no response is required, and thus are denied.

11. Upon information and belief, MLL and Micro Labs USA are agents of each other and/or operate in concert as integrated parts of the same business group.

ANSWER: Paragraph 11 of the First Amended Complaint contains conclusions of law to which no response is required and are therefore denied.

12. On information and belief, MLL and Micro Labs USA work together with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products.

ANSWER: Paragraph 12 of the First Amended Complaint contains conclusions of law to which no response is required and are therefore denied.

13. Upon information and belief, MLL and Micro Labs USA acted in concert to prepare and submit ANDA No. 219182 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the "Micro Labs ANDA Product") prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 13 of the First Amended Complaint contains conclusions of law to which no response is required and are therefore denied.

14. On information and belief, MLL and Micro Labs USA acted in concert to develop and seek regulatory approval from the FDA to market and sell the Micro Labs ANDA Product throughout the United States, including in New Jersey.

ANSWER: Paragraph 14 of the First Amended Complaint contains conclusions of law to which no response is required and are therefore denied.

15. On information and belief, MLL and Micro Labs USA intend to act collaboratively to obtain approval for Micro Labs' ANDA No 219182, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Micro Labs ANDA Product in the United States, including in New Jersey.

ANSWER: Paragraph 15 of the First Amended Complaint contains conclusions of law to which no response is required and are therefore denied.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 16 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, Micro Labs does not contest jurisdiction solely for Plaintiff's purported claims against Micro Labs. Micro Labs denies all remaining allegations of paragraph 16.

17. This Court has personal jurisdiction over Micro Labs USA because, on information and belief, Micro Labs USA is a company organized and existing under the laws of the state of New Jersey, is qualified to do business in New Jersey, and has its principal place of business in New Jersey.

ANSWER: Paragraph 17 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, Micro Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 17.

18. In view of the foregoing, Micro Labs USA is subject to general personal jurisdiction in New Jersey.

ANSWER: Paragraph 18 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, Micro Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 18.

19. This Court has personal jurisdiction over MLL because MLL, in concert with its subsidiary Micro Labs USA, among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing ANDA No. 219182 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c), including in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, on information and belief, following approval of ANDA No. 219182, MLL, in concert with its subsidiary Micro Labs USA, will make, use, import, sell, and/or offer for sale the

Micro Labs ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 19 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, Micro Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 19.

20. This Court also has personal jurisdiction over MLL because, among other things, this action arises from MLL's, and its subsidiary Micro Labs USA's, actions directed toward New Jersey, and because, upon information and belief, MLL, and its subsidiary Micro Labs USA, have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by marketing pharmaceutical products in New Jersey. MLL has therefore purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

ANSWER: Paragraph 20 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, Micro Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 20.

21. In addition, this Court has personal jurisdiction over MLL because, among other things, on information and belief, (1) MLL and its subsidiary Micro Labs USA filed Micro Labs' ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of the Micro Labs ANDA Product in the United States, including in New Jersey, and (2) upon approval of Micro Labs' ANDA, MLL and its subsidiary Micro Labs USA will market, distribute, offer for sale, sell, and/or import the Micro Labs ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Micro Labs ANDA Product in New Jersey. On information and belief, upon approval of Micro Labs' ANDA, the Micro Labs ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

ANSWER: Paragraph 21 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, Micro

Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 21.

22. This Court also has personal jurisdiction over Micro Labs USA and MLL because both Micro Labs USA and MLL regularly engage in patent litigation in this forum, including in *Aerie Pharmaceuticals, Inc. v. Micro Labs Ltd.*, C.A. No. 22-cv-01365 (D.N.J. filed Mar. 14, 2022), *Allergan Sales, LLC v. Micro Labs Ltd.*, C.A. No. 19-cv-09759 (D.N.J. filed Apr. 12, 2019), *Takeda GmbH v. Micro Labs USA, Inc.*, CA. No. 15-cv-07921 (D.N.J. filed Nov. 5, 2015).

ANSWER: Paragraph 22 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the purposes of this litigation only and further states that any pleadings referenced in this paragraph speak for themselves. Micro Labs denies all remaining allegations of paragraph 22.

23. Based on the foregoing systematic and continuous contacts with New Jersey, MLL is subject to specific personal jurisdiction in New Jersey.

ANSWER: Paragraph 23 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 23.

24. On information and belief, MLL's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent MLL denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court has personal jurisdiction over MLL pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

ANSWER: Paragraph 24 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal

jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 24.

25. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Micro Labs to litigate this action in this Court, and Micro Labs is subject to personal jurisdiction in New Jersey.

ANSWER: Paragraph 25 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not object to personal jurisdiction for the purposes of this litigation only. Micro Labs denies all remaining allegations of paragraph 25.

26. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

ANSWER: Paragraph 26 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest venue in this Judicial District for the limited purposes of this action only. Micro Labs denies all remaining allegations of paragraph 26.

27. Venue is proper in this Court as to Defendant Micro Labs USA under 28 U.S.C. § 1400(b) because it is a company organized and existing under the laws of the State of New Jersey and is subject to personal jurisdiction in this Court, as set forth above, has committed acts of infringement, and, upon information and belief, will commit further acts of infringement in New Jersey.

ANSWER: Paragraph 27 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest venue in this Judicial District for the limited purposes of this action only. Micro Labs denies all remaining allegations of paragraph 27.

28. Venue is also proper in this Court for Defendant Micro Labs USA because it has a regular and established place of business in New Jersey at least because, upon information and belief, it (1) is organized under the laws of New Jersey; (2) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities; and (3) has acted in concert with MLL to prepare and file its ANDA, and to seek approval from the FDA to market and sell the Micro Labs ANDA Product in the United States, including in New Jersey.

ANSWER: Paragraph 28 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest venue in this Judicial District for the limited purposes of this action only. Micro Labs denies all remaining allegations of paragraph 28.

29. Venue is proper in this Court as to MLL under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, MLL is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

ANSWER: Paragraph 29 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest venue in this Judicial District for the limited purposes of this action only. Micro Labs denies all remaining allegations of paragraph 29.

30. Venue is also proper in this Court for Defendant MLL because it has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell Defendants' proposed generic NEXLETOL® product in New Jersey; (2) acted in concert with Micro Labs USA in New Jersey to prepare and file its ANDA; (3) has engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities; and (4) has a New Jersey subsidiary, Micro Labs USA, through which it will make, use, import, sell, and/or offer for sale Defendants' proposed generic NEXLETOL® product in the United States, including in New Jersey.

ANSWER: Paragraph 30 of the First Amended Complaint contains conclusions of law and allegations to which no response is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Micro Labs does not contest venue in this Judicial District for the limited purposes of this action only. Micro Labs denies all remaining allegations of paragraph 30.

THE PATENTS-IN-SUIT

31. U.S. Patent No. 11,760,714 ("the '714 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on September 19, 2023. A true and correct copy of the '714 Patent is attached hereto as "Exhibit A."

ANSWER: Paragraph 31 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent that an answer may be required, Micro Labs admits that what purports to be a copy of the '714 patent is attached as Exhibit A of the First Amended Complaint, that the patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same" and that the patent bears an issue date of September 19, 2023. Micro Labs denies all remaining allegations of paragraph 31.

32. Esperion is the assignee of, and holds all rights, title, and interest in the '714 patent.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 32, and on that basis denies these allegations.

33. The '714 Patent currently expires on June 19, 2040.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 33, and on that basis denies these allegations.

34. U.S. Patent No. 11,613,511 ("the '511 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 28, 2023. A true and correct copy of the '511 Patent is attached hereto as "Exhibit B."

ANSWER: Paragraph 34 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent that an answer may be required,

Micro Labs admits that what purports to be a copy of the '511 patent is attached as Exhibit B of the First Amended Complaint, that the patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same" and that the patent bears an issue date of March 28, 2023. Micro Labs denies all remaining allegations of paragraph 34.

35. Esperion is the assignee of, and holds all rights, title, and interest in the '511 patent.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 35, and on that basis denies these allegations.

36. The '511 Patent currently expires on June 19, 2040.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 36, and on that basis denies these allegations.

37. U.S. Patent No. 11,926,584 (the "'584 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 12, 2024. A true and correct copy of the '584 Patent is attached hereto as "Exhibit C."

ANSWER: Paragraph 37 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent that an answer may be required, Micro Labs admits that what purports to be a copy of the '584 patent is attached as Exhibit C of the First Amended Complaint, that the patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same" and that the patent bears an issue date of March 12, 2024. Micro Labs denies all remaining allegations of paragraph 37.

38. Esperion is the assignee of, and holds all rights, title, and interest in the '584 Patent.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 38, and on that basis denies these allegations

39. The '584 Patent currently expires on June 19, 2040.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 39, and on that basis denies these allegations

40. All claims of the '714, '511, and '584 Patents are valid, enforceable, and not expired.

ANSWER: Denied.

ESPERION'S NEXLETOL PRODUCT

41. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL®.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 41, and on that basis denies these allegations.

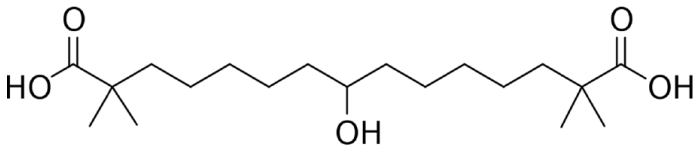
42. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL®." Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 42, and on that basis denies these allegations.

43. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 43, and on that basis denies these allegations.

44. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL®, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



ANSWER: Micro Labs admits that, according to the final printed labeling approved by the U.S. Food & Drug Administration, NEXLETOL® contains bempedoic acid and states that the chemical name for bempedoic acid is 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and includes a structural formula representation. All remaining allegations of paragraph 44 are denied.

45. The claims of the Asserted Patents cover NEXLETOL®.

ANSWER: Denied.

46. The Asserted Patents have been listed in connection with NEXLETOL® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

ANSWER: Paragraph 46 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent that an answer may be required, Micro Labs admits that FDA's Orange Book lists the '714 patent, the '511 patent, and the '584 patent in connection with NEXLETOL®. Micro Labs denies all remaining allegations of paragraph 46.

MICRO LABS' ANDA PRODUCT

47. By letter dated March 25, 2024, and received by Esperion via Federal Express no earlier than on March 26, 2024 (the "First Notice Letter"), Micro Labs notified Esperion that Micro Labs had submitted ANDA No. 219182 to the FDA for a generic version of NEXLETOL®.

ANSWER: Paragraph 47 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits to notifying Esperion Therapeutics, Inc. ("Esperion") by letter dated March 25, 2024 ("Micro Labs' First Notice Letter") that Micro Labs submitted to the FDA an ANDA under Section 505(j) of the Act seeking approval for the Micro Labs ANDA Product prior to the expiration of the '714 patent and the '511 patent. Micro Labs denies the remaining allegations of paragraph 47.

48. The First Notice Letter states that Micro Labs seeks approval from the FDA to engage in the commercial manufacture, use, and sale of the Micro Labs ANDA product before the expiration of the '714 and '511 Patents. Upon information and belief, Micro Labs intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Micro Labs ANDA product promptly upon receiving FDA approval to do so.

ANSWER: Micro Labs admits that Micro Labs' First Notice Letter dated March 25, 2024, states that Micro Labs certified to the FDA that the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product, and that Micro Labs seeks to obtain approval to engage in the commercial manufacture, use, and sale of the Micro Labs ANDA Product before the applicable expiration dates. All remaining allegations of paragraph 48 are denied.

49. By submitting ANDA No. 219182, Micro Labs has represented to the FDA that the Micro Labs ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

ANSWER: Denied.

50. In the First Notice Letter, Micro Labs stated that ANDA No. 219182 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '714 and '511 Patents. Micro Labs also contended that the '714 and '511 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Micro Labs' ANDA Product.

ANSWER: Paragraph 50 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that Micro Labs ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product. Micro Labs further admits that the Detailed Statements in Micro Labs' First Notice Letter contained factual and legal bases for Micro Labs' contention that the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product. All remaining allegations of paragraph 50 are denied.

51. Upon information and belief, Micro Labs had knowledge of the '714 and '511 Patents when it submitted ANDA No. 219182 to the FDA.

ANSWER: Paragraph 51 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that Micro Labs ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product. All remaining allegations of paragraph 51 are denied.

52. Upon information and belief, Micro Labs intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product immediately and imminently upon approval of ANDA No. 219182 and prior to expiration of the '714 and '511 Patents.

ANSWER: Micro Labs admits that Micro Labs' First Notice Letter dated March 25, 2024, states that Micro Labs certified to the FDA that the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product, and that Micro Labs seeks to obtain approval to engage in the commercial manufacture, use, and sale of the Micro Labs ANDA Product before the applicable expiration dates. All remaining allegations of paragraph 52 are denied.

53. On or about April 26, 2024, pursuant to an Offer of Confidential Access set forth in the First Notice Letter, Micro Labs produced portions of its ANDA No. 219182 to Esperion. Micro Labs refused to produce the entirety of ANDA No. 219182 to Esperion and refused to provide samples of its ANDA Product or components.

ANSWER: Micro Labs admits that on April 26, 2024, Micro Labs provided access to Micro Labs ANDA bearing bates numbers ML_BEMPEDOIC_ACID_000001 - ML_BEMPEDOIC_ACID_020542, pursuant to an Offer of Confidential Access between Esperion and Micro Labs, executed on April 23, 2024. All remaining allegations of paragraph 53 are denied.

54. Esperion filed the original complaint in this action on May 8, 2024, which was before the expiration of forty-five days from the date of Esperion's receipt of the First Notice Letter.

ANSWER: Paragraph 54 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required.

55. On or about March 12, 2024, the U.S. Patent and Trademark Office issued the '584 patent.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 55, and on that basis denies these allegations.

56. On or about April 9, 2024, and within thirty days of issuance of the '584 patent, Esperion submitted Form 3542 identifying the '584 patent for listing in the Orange Book for NEXLETOL®.

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 56, and on that basis denies these allegations.

57. On information and belief, at some point on or after April 9, 2024, during the pendency of Micro Labs' ANDA, Micro Labs provided to the FDA a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent.

ANSWER: Paragraph 57 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that Micro Labs ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '584 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product. All remaining allegations of paragraph 57 are denied.

58. By letter dated June 5, 2024, and received by Esperion via email on June 5, 2024, and via Federal Express no earlier than on June 6, 2024 (the "Second Notice Letter"), Micro Labs sent written notice to Esperion of its Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent. In the Second Notice Letter, Micro Labs contended that the '584 Patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use, and/or sale of the Micro Labs ANDA Product.

ANSWER: Paragraph 58 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that Micro Labs ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '584 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product. Micro Labs further admits to notifying Esperion by letter dated June 5, 2024 ("Micro Labs' Second Notice Letter") that Micro Labs submitted to the FDA an ANDA under Section 505(j) of the Act seeking approval for the Micro Labs ANDA Product prior to the expiration of the '584 patent. Micro Labs further admits that the Detailed Statements in Micro Labs' Second Notice Letter contained factual and legal bases for Micro Labs' contention that the '584 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product. All remaining allegations of paragraph 58 are denied.

59. Upon information and belief, Micro Labs had knowledge of the '584 Patent since at least April 9, 2024, and certainly before June 5, 2024.

ANSWER: Paragraph 59 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent Micro Labs is required to answer, Micro Labs admits that Micro Labs ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '584 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product. All remaining allegations of paragraph 59 are denied.

60. Upon information and belief, Micro Labs intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product immediately and imminently upon approval of ANDA No. 219182 and prior to expiration of the '584 Patent.

ANSWER: Micro Labs admits that Micro Labs' Second Notice Letter dated June 5, 2024, states that Micro Labs certified to the FDA that the '584 patent is invalid, unenforceable, and/or

will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product, and that Micro Labs seeks to obtain approval to engage in the commercial manufacture, use, and sale of the Micro Labs ANDA Product before the applicable expiration dates. All remaining allegations of paragraph 60 are denied.

61. This First Amended Complaint is being filed before the expiration of the forty-five days from the date of Esperion's receipt of the Second Notice Letter and prior to Micro Labs' answer to the original complaint filed May 8, 2024.

ANSWER: Paragraph 61 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required.

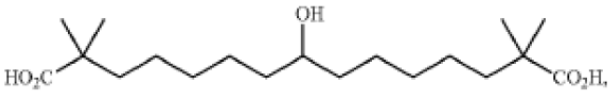
COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714

62. Esperion incorporates each of the preceding paragraphs 1-61 as if fully set forth herein.

ANSWER: Micro Labs incorporates its Answers to paragraphs 1 – 61 as if fully set forth herein.

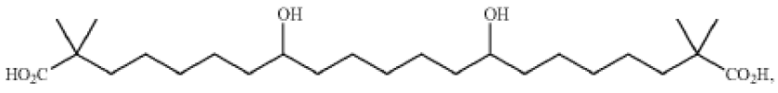
63. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(V)



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):

(VI)



and a pharmaceutically acceptable excipient.

ANSWER: Paragraph 63 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent an answer is required, Micro Labs

admits that what purports to be a copy of the '714 patent is attached as Exhibit A of the First Amended Complaint, that the patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same" and that the patent bears an issue date of September 19, 2023. Micro Labs further admits that Exhibit A includes a claim 1. All remaining allegations of this paragraph 63 are denied.

64. Micro Labs' submission of ANDA No. 219182 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

65. Micro Labs' commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product prior to expiration of the '714 Patent, and Micro Labs' inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

66. Upon information and belief, upon FDA approval of ANDA No. 219182, Micro Labs intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

67. Upon information and belief, by virtue of their listing in the Orange Book and its First Notice Letter, Micro Labs has knowledge of the '714 Patent and knowledge that its Micro Labs ANDA Product will infringe the '714 Patent.

ANSWER: Denied.

68. Upon information and belief, Micro Labs intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219182 is approved by marketing the Micro Labs ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

ANSWER: Denied.

69. Upon information and belief, Micro Labs intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA

No. 219182 is approved, unless enjoined by the Court, because Micro Labs knows that the Micro Labs ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Micro Labs ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

70. Micro Labs infringement is imminent because, among other things, Micro Labs has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product before the expiration of the '714 Patent.

ANSWER: Denied.

71. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

ANSWER: Denied.

72. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Micro Labs' making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

73. Unless Micro Labs is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

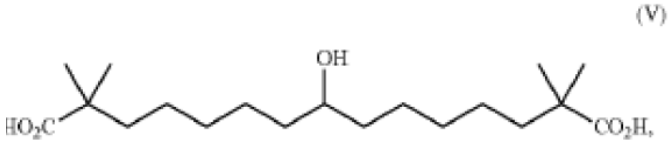
ANSWER: Denied.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

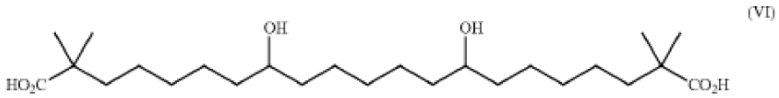
74. Esperion incorporates each of the preceding paragraphs 1-73 as if fully set forth herein.

ANSWER: Micro Labs incorporates each of its Answers to paragraphs 1 – 73 as if fully set forth herein.

75. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



(VI)

and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3±0.2, 10.4±0.2, 17.9±0.2, 18.8±0.2, 19.5±0.2, and 20.7±0.2.

ANSWER: Paragraph 75 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent an answer is required, Micro Labs admits that what purports to be a copy of the '511 patent is attached as Exhibit B of the First Amended Complaint, that the patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same" and that the patent bears an issue date of March 28, 2023. Micro Labs further admits that Exhibit B includes a claim 1. All remaining allegations of this paragraph 75 are denied.

76. Micro Labs' submission of ANDA No. 219182 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

77. Micro Labs' commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product prior to expiration of the '511 Patent, and Micro Labs' inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

78. Upon information and belief, upon FDA approval of ANDA No. 219182, Micro Labs intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, unless enjoined by the Court.

ANSWER: Denied.

79. Upon information and belief, by virtue of their listing in the Orange Book and its First Notice Letter, Micro Labs has knowledge of the '511 Patent and knowledge that its Micro Labs ANDA Product will infringe the '511 Patent.

ANSWER: Denied.

80. Upon information and belief, Micro Labs intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219182 is approved by marketing the Micro Labs ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

ANSWER: Denied.

81. Upon information and belief, Micro Labs intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219182 is approved, unless enjoined by the Court, because Micro Labs knows that the Micro Labs ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Micro Labs ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

82. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

ANSWER: Denied.

83. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Micro Labs' making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

84. Unless Micro Labs is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

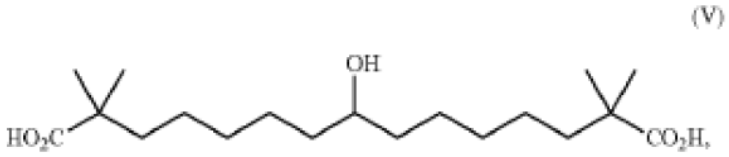
ANSWER: Denied.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,926,584

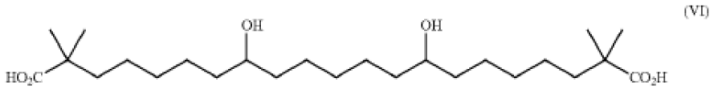
85. Esperion incorporates each of the preceding paragraphs 1-84 as if fully set forth herein.

ANSWER: Micro Labs incorporates each of its Answers to paragraphs 1 – 84 as if fully set forth herein.

86. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



ANSWER: Paragraph 86 of the First Amended Complaint contains conclusions of law and allegations to which no answer is required. To the extent an answer is required, Micro Labs admits that what purports to be a copy of the '584 patent is attached as Exhibit C of the First Amended Complaint, that the patent is titled "Methods of Making Bempedoic Acid and Compositions of the Same" and that the patent bears an issue date of March 12, 2024. Micro Labs further admits that Exhibit C includes a claim 1. All remaining allegations of this paragraph 86 are denied.

87. Micro Labs' submission of ANDA No. 219182 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product before the expiration of the '584 Patent constituted an act of infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

88. Micro Labs' commercial manufacture, use, offer for sale, sale, and/or importation of the Micro Labs ANDA Product prior to expiration of the '584 Patent, and Micro Labs'

inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

ANSWER: Denied.

89. Upon information and belief, upon FDA approval of Micro Labs' ANDA No. 219182, Micro Labs will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Micro Labs ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

ANSWER: Denied.

90. Upon information and belief, Micro Labs specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219182 is approved by marketing the Micro Labs ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

ANSWER: Denied.

91. Upon information and belief, Micro Labs' ANDA No. 219182 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Micro Labs ANDA Product.

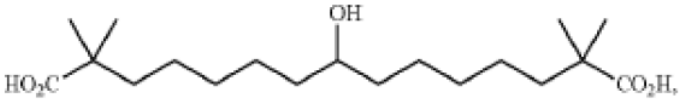
ANSWER: Denied.

92. Upon information and belief, upon FDA approval of ANDA No. 219182, Micro Labs intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, unless enjoined by the Court, and the Micro Labs ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

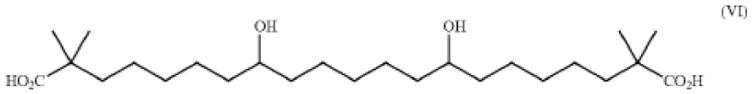
ANSWER: Denied.

93. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(V)



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



(VI)

ANSWER: Micro Labs lacks the knowledge of information sufficient to form a belief as to the truth of the allegations contained in paragraph 93, and on that basis denies these allegations.

94. Upon information and belief, the use of the Micro Labs ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Denied.

95. Upon information and belief, by virtue of its listing in the Orange Book and identification in Micro Labs' Second Notice Letter, Micro Labs has knowledge of the '584 Patent and knowledge that its Micro Labs ANDA Product will infringe the '584 Patent.

ANSWER: Denied.

96. On information and belief, Micro Labs is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Micro Labs ANDA Product at least according to Micro Labs' proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

ANSWER: Denied.

97. Upon information and belief, Micro Labs intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219182 is approved, unless enjoined by the Court, because Micro Labs knows that the Micro Labs ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Micro Labs ANDA Product is not suitable for substantial noninfringing use.

ANSWER: Denied.

98. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

ANSWER: Denied.

99. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Micro Labs' making, using, offering to sell, selling, and/or importing the Micro Labs ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

100. Unless Micro Labs is enjoined from directly or indirectly infringing the '584 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

ANSWER: Denied.

PRAYER FOR RELIEF

Micro Labs denies all allegations not expressly admitted herein. Micro Labs further denies that Plaintiff is entitled to any of the relief requested, and requests Plaintiff's First Amended Complaint be dismissed with prejudice and that Micro Labs be awarded its fees and costs incurred defending this suit under 35 U.S.C. § 285.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its ANSWER, without admitting allegations of the First Amended Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Micro Labs avers and asserts the following separate defenses to the First Amended Complaint.

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '714 PATENT)

The claims of the '714 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '714 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs' ANDA No. 219182 does not and will not infringe, either or literally or under the doctrine of equivalents, any valid and enforceable claim of the '714 patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '714 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs' ANDA No. 219182 does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '714 patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '511 PATENT)

The claims of the '511 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '511 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs' ANDA No. 219182 does not and will not infringe, either or literally or under the doctrine of equivalents, any valid and enforceable claim of the '511 patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '511 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs' ANDA No. 219182 does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '511 patent.

SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '584 PATENT)

The claims of the '584 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

EIGHTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '584 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs' ANDA No. 219182 does not and will not infringe, either or literally or under the doctrine of equivalents, any valid and enforceable claim of the '584 patent.

NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '584 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in Micro Labs' ANDA No. 219182 does not and will not induce the infringement of, and has not, does not, and will not contribute to the infringement of any valid and enforceable claim of the '584 patent.

TENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's First Amended Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

ELEVENTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiff's First Amended Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), (c), and/or (g).

TWELFTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL OR WILLFUL INFRINGEMENT)

Plaintiff's fail to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Micro Labs reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Micro Labs Limited and Micro Labs, USA, Inc. (collectively "Micro Labs"), by way of its attorneys, hereby states for its Counterclaims against Plaintiff Esperion Therapeutics, Inc. ("Esperion" or "Plaintiff/Counterclaim-Defendant"), the following:

1. Micro Labs repeats and incorporates by reference each of the foregoing paragraphs of Micro Labs' Answer and Separate Defenses to the First Amended Complaint.

PARTIES

2. Micro Labs Limited is a company organized and existing under the laws of India, and has a principal place of business at 31, Race Course Road, Bangalore-560-001, India.

3. Micro Labs USA, Inc. is a New Jersey corporation having a place of business at 220 Davidson Avenue, Suite 402 Somerset, NJ 08873.

4. Upon information and belief, Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

JURISDICTION

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and

2202, based on an actual controversy between Micro Labs and Plaintiff/Counterclaim-Defendant, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

7. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiff/ Counterclaim-Defendant is doing business in this jurisdiction.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

FACTUAL BACKGROUND

9. This is an action for declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent No. 11,760,714 ("the '714 patent"), U.S. Patent No. 11,613,511 ("the '511 patent") and U.S. Patent No. 11,926,584 ("the '584 patent") (collectively, the "Asserted Patents").

10. Upon information and belief, true and correct copies of the Asserted Patents are attached to Plaintiff's/Counterclaim-Defendant's First Amended Complaint as Exhibits A, B and C, respectively.

11. The '714 patent, which the Plaintiff/Counterclaim-Defendant alleges is attached to the First Amended Complaint as Exhibit A, on its face is titled "Methods of Making Bempedoic Acid and Compositions of the Same," and lists an issue date of September 19, 2023. The face of the '714 patent identifies Esperion Therapeutics, Inc as assignee.

12. The '511 patent, which the Plaintiff/Counterclaim-Defendant alleges is attached to the First Amended Complaint as Exhibit B, on its face is titled "Methods of Making Bempedoic Acid and Compositions of the Same," and lists an issue date of March 28, 2023. The face of the '511 patent identifies Esperion Therapeutics, Inc as assignee.

13. The ’584 patent, which the Plaintiff/Counterclaim-Defendant alleges is attached to the First Amended Complaint as Exhibit C, on its face is titled “Methods of Making Bempedoic Acid and Compositions of the Same,” and lists an issue date of March 12, 2024. The face of the ’584 patent identifies Esperion Therapeutics, Inc. as assignee.

14. Esperion Therapeutics, Inc. is the holder of New Drug Application (“NDA”) No. 211616 for the manufacture and sale of bempedoic acid, 180 mg tablets, NEXLETOL, which has been approved by the FDA.

15. Plaintiff/Counterclaim-Defendant purports and claims to have the right to enforce the Asserted Patents and has listed or caused to be listed the ’714 patent, the ’511 patent and the ’584 patent in the FDA’s *Approved Drug Products and Therapeutic Equivalence Evaluations* (the “Orange Book”) for NEXLETOL.

16. Micro Labs has filed the Abbreviated New Drug Application (“ANDA”) No. 219182 with the U.S. Food and Drug Administration (the “FDA”) seeking approval for Micro Labs’ proposed bempedoic acid tablets described therein (“Micro Labs ANDA Product”), identifying NDA No. 211616 as the Reference Listed Drug.

17. Micro Labs’ ANDA No. 219182 (“Micro Labs’ ANDA”) seeks FDA approval to market the Micro Labs ANDA Product described therein before the expiration of the Asserted Patents, and includes a certification under 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV) (also called a “Paragraph IV Certification”) as to the Asserted Patents.

18. Micro Labs notified Esperion by letter dated March 25, 2024 (“Micro Labs’ First Notice Letter”) that Micro Labs submitted to the FDA an ANDA under Section 505(j) of the Act seeking approval for the Micro Labs ANDA Product prior to the expiration of the ’714 patent and the ’511 patent and providing a Detailed Statement containing factual and legal bases for

Micro Labs' contention that the '714 and '511 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product.

19. Micro Labs notified Esperion by letter dated June 5, 2024 ("Micro Labs' Second Notice Letter") that Micro Labs submitted to the FDA an ANDA under Section 505(j) of the Act seeking approval for the Micro Labs ANDA Product prior to the expiration of the '584 patent and providing a Detailed Statement containing factual and legal bases for Micro Labs' contention that the '584 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Micro Labs ANDA Product.

20. Plaintiff/Counterclaim Defendant sued Micro Labs in this District for alleged infringement of the Asserted Patents.

COUNT I
Declaratory Judgment of Invalidity of the '714 Patent

21. Micro Labs realleges and incorporates by reference the allegations of paragraphs 1 – 20 of these Counterclaims as though fully set forth herein.

22. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '714 patent.

23. The claims of the '714 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation, at least for the reasons stated in Micro Labs' First Notice Letter.

24. For example, as described in Micro Labs' First Notice Letter, at least claims 1-20 of the '714 patent are anticipated under 35 U.S.C. § 102 by the prior art.

25. Additionally, as described in Micro Labs' First Notice Letter, at least claims 1-20 of the '714 patent are invalid under 35 U.S.C. § 103 as obvious in view of the prior art.

26. Additionally, as described in Micro Labs' First Notice Letter, at least claims 1, 4-9, 10-11, 13-16, and 18- 20 of the '714 patent are not enabled and are invalid under 35 U.S.C. § 112, ¶ 1.

27. Additionally, as described in Micro Labs' First Notice Letter, at least claims 1, 4-9, 10-11, 13-16, 18, 19, and 20 of the '714 patent lack sufficient written description and are invalid under 35 U.S.C. § 112, ¶ 1.

28. Additionally, as described in Micro Labs' First Notice Letter, at least claims 2, 3, 8, 12, 14 and 17 of the '714 patent are indefinite and invalid under 35 U.S.C. § 112, ¶ 2.

29. Micro Labs is entitled to a declaration that the claims of the '714 patent are invalid.

COUNT II
Declaratory Judgment of Non-Infringement of the '714 Patent

30. Micro Labs realleges and incorporates by reference paragraphs 1-29 of these Counterclaims as though fully set forth herein.

31. The manufacture, use, sale, offer for sale, or importation into the United States of the Micro Labs ANDA Product that is the subject of ANDA No. 219182 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '714 patent and therefore does not infringe, either directly or indirectly, the '714 patent.

32. Micro Labs is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation into the United States of the Micro Labs ANDA Product that is the subject of ANDA No. 219182 has not infringed, does not infringe, and would not, if marketed, infringe either directly or indirectly any valid or enforceable claim of the '714 patent.

COUNT III
Declaratory Judgment of Invalidity of the '511 Patent

33. Micro Labs realleges and incorporates by reference the allegations of paragraphs 1 – 32 of these Counterclaims as though fully set forth herein.

34. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '511 patent.

35. The claims of the '511 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation, at least for the reasons stated in Micro Labs' First Notice Letter.

36. For example, as described in Micro Labs' First Notice Letter, at least claims 1-17 of the '511 patent are anticipated under 35 U.S.C. § 102 by the prior art.

37. Additionally, as described in Micro Labs' First Notice Letter, at least claims 1-17 of the '511 patent are invalid under 35 U.S.C. § 103 as obvious in view of the prior art.

38. Additionally, as described in Micro Labs' First Notice Letter, at least claims 1-17 of the '511 patent are indefinite and invalid under 35 U.S.C. § 112, ¶ 2.

39. Micro Labs is entitled to a declaration that the claims of the '511 patent are invalid.

COUNT IV
Declaratory Judgment of Non-Infringement of the '511 Patent

40. Micro Labs realleges and incorporates by reference paragraphs 1-39 of these Counterclaims as though fully set forth herein.

41. The manufacture, use, sale, offer for sale, or importation into the United States of the Micro Labs ANDA Product that is the subject of ANDA No. 219182 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '511 patent and therefore does not infringe, either directly or indirectly, the '511 patent.

42. Micro Labs is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation into the United States of the Micro Labs ANDA Product that is the subject of ANDA No. 219182 has not infringed, does not infringe, and would not, if marketed, infringe either directly or indirectly any valid or enforceable claim of the '511 patent.

COUNT V
Declaratory Judgment of Invalidity of the '584 Patent

43. Micro Labs realleges and incorporates by reference the allegations of paragraphs 1 – 42 of these Counterclaims as though fully set forth herein.

44. There is an actual, substantial, and continuing case or controversy between Micro Labs and the Plaintiff/Counterclaim-Defendant regarding, *inter alia*, the invalidity of the '584 patent.

45. The claims of the '584 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, double patenting or other judicially created bases for invalidation, at least for the reasons stated in Micro Labs' Second Notice Letter.

46. For example, as described in Micro Labs' Second Notice Letter, at least claims 1-7, 9-12 and 14-19 of the '584 patent are anticipated under 35 U.S.C. § 102 by the prior art.

47. Additionally, as described in Micro Labs' Second Notice Letter, at least claims 1-20 of the '584 patent are invalid under 35 U.S.C. § 103 as obvious in view of the prior art.

48. Additionally, as described in Micro Labs' Second Notice Letter, at least claims 1, 3-8 and 14-20 of the '584 patent are not enabled and are invalid under 35 U.S.C. § 112, ¶ 1.

49. Additionally, as described in Micro Labs' Second Notice Letter, at least claims 1 and 3-20 of the '584 Patent lack sufficient written description and are invalid under 35 U.S.C. § 112, ¶ 1.

50. Additionally, as described in Micro Labs' Second Notice Letter, at least claims 2, 7 and 12 of the '584 patent are indefinite and invalid under 35 U.S.C. § 112, ¶ 2.

51. Micro Labs is entitled to a declaration that the claims of the '584 patent are invalid.

COUNT VI
Declaratory Judgment of Non-Infringement of the '584 Patent

52. Micro Labs realleges and incorporates by reference paragraphs 1-51 of these Counterclaims as though fully set forth herein.

53. The manufacture, use, sale, offer for sale, or importation into the United States of the Micro Labs ANDA Product that is the subject of ANDA No. 219182 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '584 patent and therefore does not infringe, either directly or indirectly, the '584 patent.

54. Micro Labs is entitled to a declaration that the manufacture, use, sale, offer for sale, or importation into the United States of the Micro Labs ANDA Product that is the subject of ANDA No. 219182 has not infringed, does not infringe, and would not, if marketed, infringe either directly or indirectly any valid or enforceable claim of the '584 patent.

PRAYER FOR RELIEF

Wherefore, Micro Labs respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiff/Counterclaim-Defendant as follows:

A. Declaring that the manufacture, use, sale, offer for sale, importation into the United States of the Micro Labs' ANDA Product that is the subject of ANDA No. 219182 has not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe any valid or enforceable claim of the '714 patent, either literally or under the doctrine of equivalents.

B. Declaring that the manufacture, use, sale, offer for sale, importation into the United States of the Micro Labs' ANDA Product that is the subject of ANDA No. 219182 has not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe any valid or enforceable claim of the '511 patent, either literally or under the doctrine of equivalents.

C. Declaring that the manufacture, use, sale, offer for sale, importation into the United States of the Micro Labs' ANDA Product that is the subject of ANDA No. 219182 has not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe any valid or enforceable claim of the '584 patent, either literally or under the doctrine of equivalents.

D. Declaring the claims of the '714 patent invalid;

E. Declaring the claims of the '511 patent invalid;

F. Declaring the claims of the '584 patent invalid;

G. Declaring the Food & Drug Administration may approve Abbreviated New Drug Application No. 219182 concerning Micro Labs' ANDA Product whenever the application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the Asserted Patents are invalid or not infringed pursuant to 21 U.S.C. § 355(j)(5)B)(iii)(I)(aa); and that the thirty-month period referred to in 21 U.S.C. § 355(j)(5)(B)(iii) and any other marketing exclusivity periods to which Plaintiff/Counterclaim-Defendant might otherwise be entitled (including any pediatric exclusively) are shortened to expire upon the date of entry of judgment in this case;

H. Ordering that Plaintiff's/Counterclaim-Defendant's First Amended Complaint be dismissed with prejudice and judgment entered in favor of Micro Labs;

I. If the facts so demonstrate, declaring this case exceptional and awarding Micro Labs its reasonable attorneys' fees, expenses, and costs under 35 U.S.C. § 285, this Court's inherent authority and/or any other applicable authority;

J. Ordering that Plaintiff/Counterclaim-Defendant, and its officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it or any of them, be preliminarily and permanently enjoined from using any one or more of the Asserted Patents to block, hamper, hinder, or obstruct FDA approval of the products described in ANDA No. 219182; and

K. Awarding such other relief that the Court deems just and proper under the circumstances.

MIDLIGE RICHTER LLC
Attorneys for Defendants

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Dated: July 12, 2024

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the same drug and patents are at issue in the following actions currently pending in this District:

- *Esperion Therapeutics, Inc. v. Renata Limited*, 2:24-cv-06017 (D.N.J.)
- *Esperion Therapeutics, Inc. v. Accord Healthcare, Inc. et al.*, 2:24-cv-06224 (D.N.J.)
- *Esperion Therapeutics, Inc. v. Alkem Laboratories, Ltd.*, 2:24-cv-06263 (D.N.J.)
- *Esperion Therapeutics, Inc. v. Aurobindo Pharma Limited, Apitoria Pharma Private Limited*, 2:24-cv-06348 (D.N.J.)
- *Esperion Therapeutics, Inc. v. MSN Pharmaceuticals, Inc., MSN Laboratories Private Limited, Apichem Laboratories Private Limited*, 2:24-cv-06386 (D.N.J.)
- *Esperion Therapeutics, Inc. v. Sandoz, Inc.*, 2:24-cv-06387 (D.N.J.)
- *Esperion Therapeutics, Inc. v. Hetero USA Inc., Hetero Labs Limited, Hetero Labs Limited Unit-V, Honour Lab Limited.*, 2:24-cv-06389 (D.N.J.)
- *Esperion Therapeutics, Inc. v. Dr. Reddys Laboratories Inc.*, 2:24-cv-06391 (D.N.J.)

Defendants are not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

s/ James S. Richter
James S. Richter

Dated: July 12, 2024

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants hereby certifies that the causes of action as asserted herein as its counterclaims seek primarily declaratory judgment relief. This action is, therefore, not appropriate for compulsory arbitration.

s/ James S. Richter
James S. Richter

Dated: July 12, 2024

CERTIFICATION OF SERVICE

The undersigned certifies and states that a true and accurate copy of the foregoing DEFENDANTS MICRO LABS LIMITED AND MICRO LABS USA, INC.'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT was served on all counsel of record by electronic mail on July 12, 2024.

s/ James S. Richter
James S. Richter

Dated: July 12, 2024